medCOMP

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Section 5 **510(k) SUMMARY** **Traditional 510K**

Submitter Information:

Submitter: MEDCOMP®
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Contact: Timothy Holwick, Regulatory Associate
Date Prepared: October 15, 2012

JUN 1 1 2013

Device Name: T3 CT
Common Name: Catheter, Hemodialysis, Triple-Lumen, Non-implanted
Classification Name: Blood Access device and accessories (a)(2)(b)(2)
C.F.R. Section: 876.5540
Classification Panel: Gastroenterology and Urology
Class: II, 78 NIE

Predicate Devices:

Primary:

K033570, T3 concurrence date September 16, 2004. Class II CFR §876.5540
K083675, Power-Trialysis™ Short Term Dialysis Catheter, concurrence date March 19, 2009. Class II CFR §876.5540
K102605, MAHURKAR™ Triple Lumen Catheter, concurrence date December 22, 2000. Class II CFR §876.5540

Secondary:

K121848, SCIII Chronoflex, concurrence date September 21, 2012. Class III CFR §876.5540
K091953, Pro-Picc CT, concurrence date September 16, 2009. Class II CFR §876.5970
K020465, Ash Split Cath II, concurrence date May 22, 2002. Class III CFR §876.5540
K981125, Silicone Tesio, concurrence date February 26, 1999. Class III CFR §876.5540
K091586, Vascu-Picc and Midline Catheters, concurrence date July 23, 2009. Class II CFR §876.5970
K070003, Power Injectable Implantable Port concurrence date May 15, 2007. Class II CFR §876.5965
K072509, Pro- Picc CT, concurrence date November 22, 2007. Class II CFR§876.5970
K053345 Pro-Line CT Power Injectable CVC, concurrence date March 17, 2006 Class II CFR §880.5970

Device Description:

The T3 CT is a triple lumen catheter with a designated lumen for power injection, infusion or pressure monitoring. Each catheter lumen terminates through an extension to a female luer-lock connector. Each extension has an in-line clamp to control fluid flow and the clamp I.D. Ring is marked with the priming volume plus power injection rate is printed on the center clamp. The transition between lumen and extension is housed within a molded hub. The hub is marked with the catheter French size, lumen length and both the company and catheter design name. The outer extensions are clear and marked with "Do Not Power Inject" and the center extension is a translucent purple pigment printed with "Power Injectable". The catheter is available with either straight or curved out extensions.

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The catheter lumen is composed of a soft, thermo-sensitive, polyurethane material with barium sulfate for radiopacity. At body temperature the catheter lumen becomes softer to reduce the risk of vessel trauma.

The catheter hub and extensions are molded from soft pliable polyurethane to increase patient comfort. The suture wing is flexible with suture holes for catheter securement.

Intended Used:

This is a hemodialysis catheter with power injection, infusion and pressure monitoring capabilities through one designated lumen.

Indications for Use:

The Medcomp® T3 ^{CT} catheter is a triple lumen catheter indicated for use in attaining short-term vascular access for hemodialysis, apheresis. The third internal lumen is intended for infusion, power injection of contrast media and central venous pressure monitoring.

The catheter is intended to be inserted in the jugular, femoral or subclavian vein as required. The maximum recommended infusion rate is 5ml/sec for power injection of contrast media.

Comparison to Predicate Devices:

The T3 ^{CT} catheter is substantially equivalent to the predicate devices in terms of intended use, materials, anatomical location, basic design, performance, labeling, manufacturing process and method of sterilization.

Performance Standards:

Performance standards have not been established by the FDA under section 514 of the Federal Food, Drug and Cosmetic Act.

Biocompatibility:

Results for all biocompatibility testing demonstrate the materials used meet the requirements of ISO 10993. All materials have been cleared under past approved 510K's.

Technological Characteristics:

The principles of operation are the same as the predicate devices. There are no new questions raised regarding the safety or effectiveness of the device.

Summary of Substantial Equivalence:

The proposed device meets the performance criteria of design verification as specified by ISO standards, guidance documents and test protocols. The proposed device has the same intended use, operation and function as the predicates. There are no differences that raise new issues of safety and effectiveness. The proposed device is substantially equivalent to the legally marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

June 11, 2013

Medcomp®
% Mr. Timothy Holwick
Regulatory Associate
1499 Delp Drive
HARLEYSVILLE PA 19438

Re: K123292
Trade/Device Name: T3^{CT}
Regulation Number: 21 CFR§ 876.5540
Regulation Name: Blood access device and accessories
Regulatory Class: II
Product Code: NIE
Dated: May 1, 2013
Received: May 2, 2013

Dear Mr. Holwick:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of Act. However, you are responsible to determine that the medical devices you use as components in the kit have either been determined as substantially equivalent under the premarket notification process (Section 510(k) of the act), or were on the market prior to May 28, 1976, the enactment date of the Medical Device Amendments. Please note: If you purchase your device components in bulk (i.e., unfinished) and further process (e.g., sterilize) you must submit a new 510(k) before including these components in your kit. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be

found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

In addition, we have determined that your device kit contains Lidocaine and Chloraprep which are subject to regulation as drugs.

Our substantially equivalent determination does not apply to the drug components of your device. We recommend you first contact the Center for Drug Evaluation and Research before marketing your device with the drug components. For information on applicable Agency requirements for marketing these drugs, we suggest you contact:

Director, Division of Drug Labeling Compliance
Center for Drug Evaluation and Research
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857
(301) 594-0101

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K123292

Device Name: T3 ^{CT}

Indications for Use:

The Medcomp® T3 ^{CT} catheter is a triple lumen catheter indicated for use in attaining short-term vascular access for hemodialysis, apheresis. The third internal lumen is intended for infusion, power injection of contrast media and central venous pressure monitoring.

The catheter is intended to be inserted in the jugular, femoral or subclavian vein as required. The maximum recommended infusion rate is 5ml/sec for power injection of contrast media.

Prescription Use X (Part 21-CFR-801-Subpart D) AND/OR Over-The-Counter Use (21-CFR-801-Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Benjamin R. Fisher -S
2013.06.11 18:14:40 -04'00'

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K123292